

NBS Area Service Center Vendor Agreement
SCOPE OF WORK
(7/1/11- 6/30/14)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goal No. 1 All newborns are screened for the heritable disorders as designated by the California Newborn Screening Program.

Goal No. 2 The newborns' physicians are notified of confirmed cases so that treatment is promptly initiated.

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
1. Newborns' physicians will be notified of all positive and inadequate test results within established time frames.	<p>*Notify each newborn's physician by phone of positive test results after notification from a State approved laboratory or GDSP:</p> <p style="text-align: center;"><i>within 24 hours of notification for</i> GALACTOSEMIA CONGENITAL ADRENAL HYPERPLASIA AMINO ACID DISORDERS (Other than PKU) FATTY ACID OXIDATION DISORDERS ORGANIC ACID DISORDERS</p> <p style="text-align: center;"><i>within 48 hours of notification for</i> PHENYLKETONURIA (PKU) PRIMARY CONGENITAL HYPOTHYROIDISM (PCH) HEMOGLOBINOPATHY BIOTINIDASE DEFICIENCY CYSTIC FIBROSIS INADEQUATES/Earlies</p> <p>*Inform physician of legal requirements for follow-up and how they can be met.</p> <p>*Assist and advise the physician in interpreting the screening test results.</p>	<p>In stated time frames</p> <p>At time of MD notification and when physicians are non-compliant</p> <p>At time of MD notification</p>	Maintain all records and documentation of compliance, including the tracking events in SIS and reports required by the State.

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Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
<p>2. The follow-up (i.e., repeat or confirmatory testing) of initial test that are positive, inadequate, obtained after a transfusion, or possibly collected early, i.e. under 12 hours of age, will occur within established time frames.</p> <p>a. For initial positives: Confirmatory specimens will be collected and sent to a lab as soon as possible but no later than 5 days after MD notification.</p> <p>b. For inadequate and early specimens: Repeat specimens will be collected and sent to lab as soon as possible but no later than 5 days after MD notification.</p> <p>c. For specimens possibly collected early: Babies verified to have been collected early (or whose age at collection could not be not be determined) will get a second NBS test.</p> <p>d. For babies verified to have been initially screened post-transfusion, whole blood DNA testing by a hemoglobin reference lab may be offered</p>	<p>*Assist the newborn's physician or hospital in obtaining blood specimens on infants whose initial specimens were positive, early, inadequate or collected after a transfusion. For early tests: Verify times/dates of birth and specimen collection.</p> <p>*Send letters to all parents and physicians of newborns requiring further actions, with the exception of newborns remaining in hospitals.</p> <p>*Provide newborn's physician with appropriate specimen collection forms and instructions for specimen collections.</p> <p>*Assist MD/hospital to collect a specimen.</p> <p>*Inform newborn's physician that a specimen was not obtained and offer assistance in arranging specimen collection.</p>	<p>At time of MD notification</p> <p>within 3 days of reporting out NBS results</p> <p>At time of MD notification</p> <p>At time of MD notification</p> <p>At time of MD notification</p>	<p>Maintain in ASC file the number of possibly early tests and inadequates, and list, by specific disease, the number of positives. - SIS BO reports</p> <p>Retain copies of letters in NBS ASC files.</p> <p>Maintain in ASC file the time required to obtain adequate samples and the number for which no sample could be obtained (i.e. lost to follow-up, refusals).</p> <p>Maintain in ASC file: - number of actual early collections - number of those flagged as possibly early that were actually collected after 12 hours.</p> <p>Tracking events, case notes</p>

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3. Babies not screened at birth will be identified, located, and screened.	*Notify parents of NBS requirements and provide assistance in arranging specimen collection.	At time of MD notification	Maintain in ASC file the number of NBS-NOs, out-of-hospital births, and missing results as well as outcomes of follow-up. case notes, SIS case notes, and reports
a. Those discharged from a hospital without a specimen obtained will have a specimen collected and sent to lab within 48 hours of MD notification.	*Offer MD/hospital assistance in arranging for specimen collection.	At time of MD notification	Maintain in ASC File the number of specimens collected/sent - results in SIS
b. Those born out of hospitals and not subsequently admitted to a hospital will have a specimen collected and sent to lab within 48 hours of notification of ASC.			
4. Consultation is provided to primary care providers regarding interpretation of the confirmatory screening test results and diagnosis and management of disorders detected.	*Provide assistance to newborns' physicians regarding referrals to appropriate CCS Centers and/or medical specialists, and recommended diagnostic procedures and treatment.	At time of MD notification	Submit any changes in NBS Medical Consultants or Medical Specialists to the State for approval. Documentation in SIS
5. Information, assistance and support is provided to parents of infants with positive, or early, inadequate tests.	*Answers parents' questions *Facilitates transportation, translation services	on-going	Documentation in SIS
6. All infants with confirmed cases are evaluated and treatment is initiated within time frames that meet State standards.	*Monitor age of newborns at initiation of treatment and identify causes for delays, defined as: > 6 days for galactosemia > 14 days for PKU > 14 days for hypothyroidism > 8 weeks for hemoglobinopathies *Contact newborn's physicians to obtain information about diagnosis and treatment. *For babies with hyperphenylalaninemia: facilitate the collection/handling of specimens for biopterin testing, when needed.	monthly on-going within 48 hours of Metabolic center specialist notification	SIS reports Corrective action plan for delays Document delays, reasons for delays in monthly report State staff reviews cases in which treatment was delayed. Document number of specimens sent for biopterin testing, Maintain in ASC file as needed.

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7. Timely transmission of data via the State's computer network will occur between the State and the Area Service Center.	*Maintain a communications device in accordance with State specifications. The computer network shall operate on specified data lines and shall provide hard copy output of transmissions.	on-going	To insure system compatibility, any proposed changes must receive prior written approval from the State.
	*Log on at least once daily to the central site computer (SIS) for reception of data, contingent upon availability of the State's computer system. Communication with the State shall be the first priority in the use of communication devices.	daily	Notify the State immediately of any problems in data transmission. Review for accuracy of data.
	*Assure proper hardware and software functioning.	daily	
	*Enter data into State's central site computer (SIS) within 24 hours of data acquisition.	on-going	State staff will monitor timeliness, completeness and accuracy of data entered, using SIS Business Object reports.
	*Enter Tracking Events and case notes documenting activities and calls between ASC, hospitals and newborn's physicians on same day of calls.	daily	
	*Upon finding or being informed that a case is resolved, enter appropriate resolution data into SIS computer record.	by the next business day	SIS Reports
8. Consultation and technical assistance is provided to NBS providers and others with NBS responsibilities, i.e. physicians, hospitals with perinatal facilities and free-standing children's hospitals, public health departments, midwives, primary care providers, etc., in implementation and interpretation of state regulations.	*Conduct site visits to each of the perinatal facilities within the region.	a minimum of once every three years	In monthly reports include: State number and names of hospitals visited including date of visit, personnel contacted and purpose and outcome of visit.
	*Provide phone and on-site consultation.	upon request or when needed	Maintain log of contacts or hospital file, as needed.
	*Communicate up-to-date information on program regulations, policies, and protocols by a variety of methods (e.g., newsletters, meetings, presentations, etc.)	on-going	Expected outcomes: Acceptable rate of inadequates. Decrease in delays in obtaining repeats or confirmatory tests, low deficiency rate on HEPP Report, Increase in NBS-OH's sent to state from registrar's offices, etc.
	*Provide reference and resource materials as needed.	when requested	All mass mailings addressing NBS Program policies and protocols must be submitted to contract liaisons for approval prior to mailing. - Contact logs Patient education materials that are not on the State approved list must be submitted to the contract liaison for review and approval prior to distribution.

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9. Education and training provided to those in newborn screening, i.e., physicians, hospital personnel, public health departments, midwives, etc.	*Assess knowledge and learning needs of target groups.	ASC Annual Plan due June 1, yearly	Submit to State for review and approval, an annual education/quality improvement plan which includes the following information: - description of region's identified learning needs and respective target audiences. - methods and tools used to assess needs - objectives - plan to address needs (i.e., informal in-services, continuing education programs, newsletters, etc.) - timelines/schedule of events (dates, length of time, locations) - method of evaluation
	*Design and present educational programs to address identified needs.	on-going	
	*Conduct at least 6 educational programs annually and more when needed.	yearly	Submit to State for approval at least two weeks prior to presentation, agenda, course outline, program length, targeted audience, goals and objectives, methodologies, copy of handouts, printout of slides and evaluation tools. (State supplied or approved course outlines and materials e.g., slides, do not need to be submitted unless modified.)
	*Evaluate effectiveness of educational strategies.	quarterly	Maintain ASC file with list of participants, copies of evaluations. - HEPP reports
10. Quality improvement activities are implemented to assure that NBS program objectives are met, problems are addressed or prevented, and evaluation is on-going.	*Develop written corrective action plans for identified problems.	when appropriate	Copies of completed corrective action plans are to be submitted to the contract liaisons in quarterly reports. - BO reports.
	*Develop corrective action plan appropriate, when time frames are not met. Monitor key milestones in follow-up of newborns as defined by GDB (e.g., time from referral to appointment at CCS Center, time to diagnosis, time to treatment, etc.). Obtain diagnosis and treatment information from baby's physician.	on-going	
	*Review Hospital Evaluation Performance Profile (HEPP) reports and distribute to facilities with ASC region.	monthly, quarterly, and annually	- HEPP reports
	*Follow-up with facilities that have significant numbers of deficiencies and/or on-going deficiencies that do not decrease over time.	monthly, and quarterly	
	*Provide on-going feedback to facilities regarding their performance and compliance with NBS regulations, policies, and protocols.	on-going	

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11. Provide input in the continuing development, implementation, and evaluation of the Newborn Screening Program.	*Attend Statewide meetings and in-service programs as required by the State. Attendance at other program meetings/conferences	on-going	Attendance records will be kept by the State. Maintain in ASC file. Written report, conference materials, and/or other items of significance.
	*Participate in ad hoc committees, Maternal PKU Camp, and special projects as requested.	on-going	Committee lists, meeting sign-in sheets and/or participant lists.